

K081297

JUN 11 2008

## VERTEX® Reconstruction System 510(k) Summary

April 2008

- I. Company:** Medtronic Sofamor Danek USA  
1800 Pyramid Place  
Memphis, Tennessee 38132  
Telephone: (901) 396-3133  
Fax: (901) 346-9738
- Contact:** Melisa Lansky, M.B.A.  
Regulatory Affairs Specialist
- II. Proposed Proprietary Trade Name:** VERTEX® Reconstruction System
- III. Classification Name(s):** Spinal Interlaminar Fixation Orthosis; Class: II; Product Code(s): KWP and Regulation No.: 888.3050
- IV. Description:** The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.
- The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and or/cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. Some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.
- To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.
- V. Indications for Use:** When intended to promote fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for the following:  
DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history

and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

***Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks***

The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.

**Note:** Segmental fixation is recommended for these constructs.

***Hooks and Rods***

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

***Multi-axial Screws/Connectors***

The use of multi-axial screws is limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

- VI. Substantial Equivalence:** Documentation was provided demonstrating that the VERTEX® Reconstruction System is substantially equivalent to other commercially available posterior fixation systems and other pre-enactment devices including the VERTEX® Reconstruction System. The results of mechanical testing performed for the subject VERTEX® Reconstruction System components were equivalent to or better than the testing performed for the predicate VERTEX® Reconstruction System components.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medtronic Sofamor Danek  
% Ms. Christine Scifert  
Director, Regulatory Affairs  
1800 Pyramid Place  
Memphis, Tennessee 38132

**JUN 11 2008**

Re: K081297  
Trade/Device Name: VERTEX<sup>®</sup> Reconstruction System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: KWP  
Dated: March 6, 2008  
Received: March 14, 2008

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K081297

Device Name: VERTEX® Reconstruction System

**Indications for Use:**

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nat R P Dzh  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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